

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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ORTHO-MCNEIL  
PHARMACEUTICAL, INC.,

Plaintiff and  
Counterclaim Defendant

v.

KALI LABORATORIES, INC.,  
PAR PHARMACEUTICAL  
COMPANIES, INC., PAR  
PHARMACEUTICAL, INC.,

Defendants and  
Counterclaimants.

ORTHO-MCNEIL  
PHARMACEUTICAL, INC.,

Plaintiff and  
Counterclaim Defendant,

v.

TEVA PHARMACEUTICAL  
INDUSTRIES, LTD., TEVA  
PHARMACEUTICALS USA, INC.,  
BARR LABORATORIES, INC.

Defendants and  
Counterclaimants.

ORTHO-MCNEIL  
PHARMACEUTICAL, INC.,

Plaintiff and  
Counterclaim Defendant

v.

CIVIL ACTION NO.: 02-5707 (DMC)

**OPINION**

CIVIL ACTION NO.: 04-0886 (DMC)

CIVIL ACTION NO.: 06-3533 (DMC)

KALI LABORATORIES, INC.,  
 PAR PHARMACEUTICAL  
 COMPANIES, INC., PAR  
 PHARMACEUTICAL, INC., BARR  
 LABORATORIES, INC., CARACO  
 PHARMACEUTICAL LABORATORIES,  
 LTD.,

Defendants and  
 Counterclaimants.

**DENNIS M. CAVANAUGH, U.S.D.J.**

Currently pending before the Court is Plaintiff Ortho-McNeil Pharmaceutical Inc.’s (“Ortho”) motion under Federal Rule of Civil Procedure 54(b) to certify an April 4, 2007 order issued by Judge John C. Lifland in civil action no. 02-5707/04-0886 as a final judgment so Ortho can immediately appeal. For the following reasons, the Court will deny that motion. Further, the Court will consolidate civil action no. 02-5707/04-0886 with a related action currently pending before the Court, civil action no. 06-3533.

**I. Background**

**A. The Claims and Summary Judgment Motion in 02-5707/04-0886**

Consolidated civil actions 02-5707 and 04-0886 are patent infringement suits involving Ortho’s pain-relief drug Ultracet. Ortho filed infringement claims under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A), against Kali Laboratories, Inc. (“Kali”) and Barr Laboratories, Inc. (“Barr”) after both Defendants filed Abbreviated New Drug Applications (“ANDA”) with the Food and Drug Association seeking approval to sell generic versions of Ultracet. Ortho alleged

that Defendants' ANDAs infringed Claim 6 of its U.S. Patent No. 5,336,691 ("the '691 patent").<sup>1</sup>

Kali and Barr responded with counterclaims against all claims of the '691 patent, not just Claim 6. Specifically, Kali asserted counterclaims seeking declarations of: (1) non-infringement of all claims of the '691 patent; (2) invalidity (based on anticipation, obviousness, indefiniteness, and the public-use bar) of all claims of the '691 patent; and (3) unenforceability of the '691 patent due to inequitable conduct. Barr asserted counterclaims seeking declarations of: (1) non-infringement of all claims of the '691 patent, and (2) invalidity (based on anticipation) of all claims of the '691 patent.

After discovery, Kali and Barr both moved for summary judgment of (1) non-infringement of only Claim 6 under § 271(e)(2)(A), and (2) invalidity of Claim 6.

## **B. The '221 Reissue Patent**

While the cases were pending, Ortho surrendered the '691 patent to the U.S. Patent and Trademark Office ("PTO"), and filed a reissue application, conceding to the PTO that certain claims of the '691 patent were anticipated by prior art. On August 1, 2006 the PTO granted Ortho U.S. Reissue Patent No. RE39,221 ("the '221 patent"), which retained only Claim 6 from the '691 patent, and added 62 additional new claims.

### **1. Ortho Files a New Infringement Suit (No. 06-3533)**

Immediately after the '221 patent reissued, Ortho filed a separate suit (No. 06-3533) against Kali, Barr, and Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), alleging actual infringement of all claims of the '221 patent, except for Claim 6. Kali and Barr responded to Ortho's new claims with counterclaims seeking declarations of non-infringement and invalidity

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<sup>1</sup> Ortho later amended both of its complaints to include actual infringement allegations under § 271(a) once Kali and Barr began selling their generic Ultracet products.

of all claims of the '221 patent. In addition, Barr seeks a declaration of unenforceability due to inequitable conduct, and a declaration of intervening rights. Caraco is not asserting counterclaims against Ortho.

**2. The Parties Amend their Pleadings in No. 02-5707/04-0886**

About two months later, in October 2006, Ortho amended its complaints in no. 02-5707 and no. 04-0886 to reflect that it was now asserting that Claim 6 of the '221 patent was infringed, instead of the '691 patent. It did not expand its infringement allegations to cover all claims of the '221 patent. In turn, Kali and Barr amended their answers to reflect that their counterclaims were now directed at all claims of the reissued '221 patent. Additionally, Kali added a counterclaim seeking a declaration of intervening rights. After this round of amending, Kali's and Barr's answers in 02-5707 and 04-0886 now assert the exact same counterclaims against Ortho as their answers in 06-3533.

**C. Judge Lifland's April 4, 2007 Summary Judgment Ruling**

After construing Claim 6 of the '221 patent, Judge Lifland made the following rulings. In no. 02-5707, Kali was granted summary judgment of non-infringement of Claim 6 under § 271(e)(2)(A), and of invalidity of Claim 6, for anticipation and obviousness. In no. 04-0886, Ortho was granted summary judgment of infringement of Claim 6 under § 271(e)(2)(A), and Barr was granted summary judgment of invalidity of Claim 6 for anticipation.

As a result of Judge Lifland's finding that Claim 6 is invalid, Ortho concedes that its claims that Claim 6 was actually infringed under § 271(a) are moot. Thus, the only claims remaining in the case are Kali's and Barr's counterclaims, which as mentioned above, are duplicative of their counterclaims in no. 06-3533. In no. 02-5707, Kali's counterclaims for

declarations of (1) non-infringement of all claims of the '221 patent except Claim 6; (2) invalidity of all claims of the '221 patent except Claim 6; (3) unenforceability of the '221 patent due to inequitable conduct; and (4) intervening rights, are still outstanding. In no. 04-0886, Barr's counterclaims for declarations of (1) non-infringement of all claims of the '221 patent except Claim 6; and (2) invalidity of all claims of the '221 patent except Claim 6, are still outstanding.

On April 30, 2007, Ortho moved under Rule 54(b) for a certification of the April 4, 2007 order as a final judgment so it could immediately appeal the decision. Kali and Barr oppose the motion.

## **II. Discussion**

### **A. The Rule 54(b) Motion**

The Rule 54(b) motion will be denied because Ortho has failed to show that there is no just reason for delaying an appeal until the resolution of the entire case.

The Federal Circuit only has appellate jurisdiction over "final decision[s]" of the district courts. 28 U.S.C. § 1295(a)(1). A decision is final where "it ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." Catlin v. United States, 324 U.S. 229 (1945). It is undisputed that the April 4, 2007 ruling was not a final decision.

Rule 54(b) is an exception to the finality rule. It provides:

When more than one claim for relief is presented in an action, whether as a claim, counterclaim, cross-claim, or third-party claim, or when multiple parties are involved, the court may direct the entry of a final judgment as to one or more but fewer than all of the claims or parties only upon an express determination that there is no just reason for delay and upon an express direction for the entry of judgment.

In order for Rule 54(b) to apply, first, “the judgment must be final with respect to one or more claims,” and second, there must be “no just reason for delay” of an appeal of those claims. See W.L. Gore & Assoc. Inc. v. Int’l Medical Prosthetics Research Assoc., Inc., 975 F.2d 858, 861-62 (Fed. Cir. 1992).

**1. Finality**

There is no debate that the April 4, 2007 order is final with respect to the claims resolved therein: Ortho’s Claim 6 infringement claims, and Barr’s and Kali’s non-infringement and invalidity counterclaims with respect to Claim 6 of the ‘221 patent.

**2. No Just Reason for Delay**

When determining whether there is no just reason for delay, the U.S. Supreme Court has instructed that a district court “must take into account judicial administrative interests” such as “the historic federal policy against piecemeal appeals.” Curtiss-Wright Corp. v. General Electric Co., 446 U.S. 1, 7 (1980). Following Curtiss-Wright, the Court of Appeals for the Third Circuit<sup>2</sup> has delineated five factors to examine when determining whether there is no just reason for delay:

“(1) the relationship between the adjudicated and unadjudicated claims; (2) the possibility that the need for review might or might not be mooted by future developments in the district court; (3) the possibility that the reviewing court might be obliged to consider the same issue a second time; (4) the presence or absence of a claim or counterclaim which could result in set-off against the judgment sought to be made final; (5) miscellaneous factors such as delay, economic and solvency considerations, shortening the time of trial, frivolity of

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<sup>2</sup> “Because construction of the Federal Rules of Civil Procedure is a matter not unique to patent law, [the Federal Circuit] normally appl[ies] the law of the regional circuit in which the district court sits.” Snellman v. Richoh, 836 F.2d 528 (Fed. Cir. 1987).

competing claims, expense, and the like.”

Berkeley Inv. Group, Ltd. v. Colkitt, 455 F.3d 195, 203 (3d Cir. 2006) (quoting Allis-Chalmers Corp. v. Phila. Elec. Co., 521 F.2d 360, 364 (3d Cir. 1975)). The “no just reason for delay” determination is subject to abuse of discretion review. W.L. Gore, 975 F.2d at 862.

**a. The Relationship Between the Adjudicated and Unadjudicated Claims**

Where the adjudicated and unadjudicated claims share significant similarities, such as involving the same parties, the same legal issues, or the same evidence, Rule 54(b) certification is disfavored. See, e.g., Carter v. City of Philadelphia, 181 F.3d 339, 343, 346 (3d Cir. 1999) (holding a Rule 54(b) certification proper, in part because the certified and uncertified claims involved different defendants); Genty v. Resolution Trust Corp., 937 F.2d 899, 906 (3d Cir. 1991) (same); Gerardi v. Pelullo, 16 F.3d 1363, 1372 (3d Cir. 1994) (reversing Rule 54(b) certification because “the facts underlying the [certified] claim . . . may be intertwined with the remaining issues”); Zavala v. Wal-Mart Stores, Inc., No. 03-5309, 2007 U.S. Dist. LEXIS 27882, at \*8-10 (D.N.J. April 14, 2007) (denying plaintiff’s Rule 54(b) motion where the same parties were involved, and the same evidence was required to prove both the adjudicated and unadjudicated claims); see also Morrison-Knudsen Co. v. Archer, 655 F.2d 962, 965 (9th Cir. 1981) (“A similarity of legal or factual issues will weigh heavily against entry of judgment under [Rule 54(b)].”). Indeed the Third Circuit has recognized that “Rule 54(b) certification is more appropriate when a party joins completely unrelated claims as permitted by Fed. R. Civ. P. 18(a), and recovers a judgment on fewer than all the claims.” Gerardi, 16 F.3d at 1372 n.16.

Here, the parties involved in the adjudicated and unadjudicated claims are identical. Additionally, the legal and factual issues in the claims similar. As Ortho itself recognizes, the claim construction of Claim 6 is directly applicable to the other claims of the '221 patent, which use much of the same language, and which are the subjects of the unadjudicated counterclaims. (See Ortho Mem. 11 (arguing for Rule 54(b) judgment because "[a] speedy appeal will allow the Federal Circuit the opportunity to correct any errors in the [April 4 decision] before those errors are further compounded by being adopted in the 2006 case").

Evidence-wise, much of the prior art pertinent to the adjudicated Claim 6 issues will also be relevant to Kali's unadjudicated inequitable conduct counterclaim, since the basis for that claim almost certainly will be Ortho's alleged failure to disclose material information about the prior art to the PTO when applying for the '691 patent. (See Kali's Amended Complaint, 02-5707 D.I. 103, ¶ 3 (alleging that Ortho misrepresented to the PTO what the prior art Flick patent disclosed in order to gain approval of the '691 patent).

Furthermore, the prior art relevant to Claim 6 is also relevant to the unadjudicated invalidity counterclaims asserted against the '221 patent's other claims.

Ortho asserts that Rule 54(b) judgment is appropriate because the adjudicated claims far outnumber the unadjudicated portion of the case. Ortho claims that the April 4 decision resolved the "central portion" of the 02-5707/04-0886 litigation, and that the suit with Barr was "effectively terminated" as a result because Barr does not have outstanding inequitable conduct and intervening rights counterclaims like Kali does. Ortho's argument ignores that Kali's and Barr's *invalidity* counterclaims attack *all 62* claims of the '221 patent other than Claim 6. Thus,



a large portion of no. 02-5707/04-0886 still awaits adjudication.

Ortho also argues that Kali's inequitable conduct and intervening rights counterclaims are "collateral" to the case, and should be dismissed or stayed pending appeal because they are moot in light of the ruling that Claim 6 is invalid. Kali, however, is not only facing a (now resolved) claim that it infringed Claim 6. Kali also faces claims that it infringed the other 62 claims of the '221 patent in the 06-3553 case, and thus, is justified in trying to prevent any delay of the resolution of the '221 patent's enforceability or of Kali's intervening rights since Kali still faces the threat of a finding of infringement of the '221 patent's claims. Although those infringement claims are in a separate case, the reality is that they exist, and as discussed further below, the 02-5707/04-0886 and 06-3553 will be consolidated in order to better reflect that reality.

**b. Possibility that Appellate Review Might Be Mooted by Future Developments in the District Court**

There is a strong possibility that Federal Circuit review of the April 4, 2007 decision could be mooted by later action by this Court. In both no. 02-5707/04-0886 and no. 06-3533 Kali has asserted an inequitable conduct counterclaim. If the Court were to agree with Kali, then the '221 patent would be unenforceable in its entirety. See Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 887 (Fed Cir. 1988). Such a decision would render moot a Federal Circuit determination that Claim 6 is in fact valid and infringed by Kali and Barr, because unenforceability is a defense to infringement. See 35 U.S.C. § 282. Even a Federal Circuit decision upholding the Claim 6 invalidity ruling would be rendered somewhat irrelevant by a finding of inequitable conduct by this Court, because invalidity and unenforceability are both

defenses to infringement.

**c. Possibility that Reviewing Court Might Be Obligated to Consider the Same Issue a Second Time**

Rule 54(b) certification will also be denied because it would result in a piecemeal appeal to the Federal Circuit. If the April 4, 2007 decision is immediately appealed, the Federal Circuit will have to evaluate whether Claim 6 of the ‘221 patent was infringed, or is invalid. Regardless of the outcome of that decision, the parties will inevitably appeal the result of the remainder of no. 02-5707/04-0886 and no. 06-3533 (regardless of whether these cases are stayed pending the appeal), and the Federal Circuit will be then forced to determine whether the other claims of the ‘221 patent are infringed, invalid, or unenforceable. This appeal would involve much of the same evidence and many of the same legal issues as the first appeal would. It would be far more efficient for the Federal Circuit to review the Court’s ruling on the possible infringement, validity, and enforceability of the entire ‘221 patent at one time. See, e.g., Wood v. GCC Bend, LLC, 422 F.3d 873, 880 (9th Cir. 2005) (reversing Rule 54(b) certification because plaintiff’s “right to legal relief [in the adjudicated and unadjudicated claims] stems largely from the same set of facts and would give rise to successive appeals that would turn largely on identical and interrelated facts”).

**d. Miscellaneous Factors**

Other factors support denying the Rule 54(b) motion.

First, Ortho has failed to allege any sort of prejudice it would face if not permitted to immediately appeal the April 4 ruling.

Second, Ortho overstates the threat that Judge Lifland's claim construction will be reversed on appeal. Ortho argues that an immediate appeal could save time because it would prevent this Court from relying upon Judge Lifland's allegedly erroneous claim construction going forward in no. 02-5707/04-0886 and no. 06-3533. Although other courts have cited the specter of the Federal Circuit's de novo review of claim construction as a reason for granting Rule 54(b) judgment, see Loral Fairchild Corp. v. Victor Co., 931 F. Supp. 1044, 1047-48 (E.D.N.Y. 1996), the Court is not troubled by proceeding in this case without intervening review of Judge Lifland's analysis. It is of particular note that Judge Lifland's claim construction rests in large part on a previous decision of the Federal Circuit that interprets the *exact same* patent claim in a suit between Ortho and Caraco in the Eastern District of Michigan. See Ortho-McNeil Pharm, Inc. v. Kali Labs, Inc., No. 02-5707/04-0886, 2007 U.S. Dist. LEXIS 25459, at \*18 (D.N.J. April 4, 2007) (citing Ortho-McNeil Pharm. Inc. v. Caraco Pharm. Labs, Ltd., 476 F.3d 1312 (Fed. Cir. 2007)).

In sum, for the preceding reasons, Ortho's motion for Rule 54(b) judgment will be denied.

**B. Civil Action No. 02-5707/04-0886 Will Be Consolidated with No. 06-3533**

Because there are overlapping issues of law and fact between no. 02-5707/04-0886 and no. 06-3533, the Court will consolidate the cases for pretrial purposes pursuant to Federal Rule of Civil Procedure 42(a).

Rule 42(a) permits the Court to consolidate "actions involving a common question of law or fact." When determining whether to consolidate, the Court should "weigh[] the interest in

judicial convenience against the potential for delay, confusion, and prejudice caused by consolidation.”<sup>3</sup> Paxonet Communs., Inc. v. Transwitch Corp., 303 F. Supp. 2d 1027, 1029, (N.D. Cal. 2003).

Here, there are common questions of fact. Both cases involve the same patent, and the same prior art. The cases also involve the same parties, with the exception of Defendant Caraco in no. 06-3553; however, it does not appear that Caraco would be prejudiced in anyway by consolidation since Ortho’s Rule 54(b) motion will be denied. There are also common questions of law. The only remaining claims in no. 02-5707/04-0886 also exist in no. 06-3533. Cf. Paxonet, 303 F. Supp. 2d at 1029 (consolidating two patent infringement actions involving two of the same parties, three of the same patents, identical claim terms, and the same underlying technology, in order to serve judicial efficiency).

Essentially, the 02-5707/04-0886 and 06-3533 cases are one patent infringement case involving all claims of one patent. Treating these cases as a whole will better enable the Court to address the remaining issues in an efficient fashion, and to lay out a comprehensive discovery plan and trial schedule for the remainder of the case.

### **III. Conclusion**

For the foregoing reasons, Ortho’s Rule 54(b) motion will be denied, and no. 02-5707/04-0886 will be consolidated with no. 06-3533 for pre-trial purposes pursuant to Rule 42(a). An appropriate order will be filed herewith.

S/ Dennis M. Cavanaugh  
DENNIS M. CAVANAUGH, U.S.D.J.

Dated: June 20, 2007

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<sup>3</sup> None of the parties has specifically asked for consolidation, although Barr’s letter brief of April 30, 2007 does hint that it would support it. In any event, the Court may consolidate *sua sponte*. See, e.g., Penn. Gas. Ins. Co. v. Landis, 96 F. Supp. 2d 408, 410 (D.N.J. 2000).